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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,407	02/05/2004	Dong-Soo Han	HAND3001/EM	2851
23364	7590	11/22/2006	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/771,407

Applicant(s)

HAN ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Status of Claims

1. Amendment filed 09/11/2006 is acknowledged. Claims 5-7 are canceled. Claims 1-4 are pending.

Applicant's arguments have been fully considered and were deemed persuasive-in-part. The following rejections objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. The term "interaction" used throughout the claims is vague and indefinite. It is not clear, what kind of interaction is meant, is it chemical, or enzymatic interaction, or forming hydrogen bonds, or hydrophobic interaction, etc?

Further, the meaning of interaction is not clear for the situation of proteins which are clearly identified in claim 1 as "non-interacting sets of protein pairs".

Response to arguments

Applicant argues that it does not matter what kind of interaction is meant and that the claims should not be limited to particular examples. Examiner is not attempting to limit the claims to particular examples (of which there are none in the specification). Rather, the issue is that the term "interacting" is essential for the "selecting" step of the method: without a clear definition of the term, one would not be ascertained of which protein pairs to address, as to be considered as "interacting" or "not-interacting" one should know the meaning of the term. For example, all proteins will have some sort of ionic or hydrophobic interaction, does it mean that all randomly taken pairs of protein are considered as "interacting" (and conversely, there will be no "non-interacting" pairs)?

- A. Claim 1, step "selecting": It is not clear how a domain pair is "selected" from a non-interacting protein pair.
- B. The term "interaction between two proteins", both in the first and last lines of claim 1 is not clear: It is not clear whether the "two proteins" are from the "interacting" or "non-interacting" set of pairs addressed in claim 1a) and in "generating" method step.
- C. The similar concern as above addresses use of the term "applying the determined function to a protein pair" in 4<sup>th</sup> line from the bottom of claim 1.

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D. Further, with regard to the term "protein pair which configures sets of proteins", it is not clear how a protein (or a protein pair) "configures" sets of proteins.

E. Claim 1, step "determining a function": The terms "a function", "a real number" and "a designated range" are not clear and the claim is failing to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. Although specification provides a particular example of "Primary Interaction Probability", PIP, which assigns to a particular protein pair a number in the range of 0 to 1 (p. 11), the terms "a function", "a real number" and "a designated range" are not defined and it is not clear what portion what function that maps a pair to a number in a designated range is encompassed by the claim.

F. Further, with respect to "determining a function", it is not clear how to determine a function. Specification addresses use of already defined function PIP, but does not define methods steps leading to "determining a function". Also, in the following step "generating", it is not clear what "determined function" is applied.

G. Claim 1, step "generating": It is not clear what "generating an storing" means.

H. Claim 1, step "generating": The phrase "...which configures" is not clear. Which of the preceding terms in the claim are meant as configuring the sets of interacting or non-interacting protein pairs, a distribution, a function, a protein pair, or applying a function to a pair? And how can any of the above "configure a set of pairs"?

I. Claim 2: the method steps of the claim lack antecedent basis as step a) of claim 1 as amended does not address appearance frequency.

***Claim Rejections - 35 USC § 112, first paragraph (New Matter)***

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1, step "generating", recites the term "prediction distribution". There is no description of such term in specification and there is no guidance on how to practice the claimed method using such term.

***Claim Rejections - 35 U.S.C. § 101 and 112-1***

4. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The rejection is maintained for the reasons of record and further in view of the following.

Applicant argues that prediction of interaction probability does not require identification of which interaction is being addressed. The issue of this rejection, however, is not whether prediction of interaction of protein is enabled, but whether predicting of unidentified interaction has an immediate specific and substantial utility. As stated in the rejection, claim which merely recites estimating the effects of an

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independent variable on a dependent variable, where the variables are not identified, would not have a utility as further research would be required to determine what the effect is.

In referring to part B on p. 3 of the Office action, applicant, again, is referring to another rejection made under 35 U.S.C. 112, second paragraph.

Further, applicant asserts that the instant method avoids limitations of Gomez's method by not seeking relation between functional interactions and frequencies of occurrences, but rather involving "a variable probability of interactions that may have multiple possibilities or embodiments". Examiner agrees that the method indeed "may have multiple possibilities or embodiments" but whether there are such "multiple possibilities" and whether they are practical remains a subject of further research. Thus, the invention lacks substantial utility.

The rejection is maintained.

5. Claims 1-4 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Applicant erroneously address the rejection as being made on the basis that the invention does not produce useful, concrete and tangible result. Rather, the rejection is made based on the lack of utility.

***Claim Rejections - 35 U.S.C. § 101***

6. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As stated in the rejection, the final result achieved by the claimed invention produces a result which does not satisfy all three criteria of being useful, and concrete, and tangible. The claimed invention is directed to an abstract method which does not address any real interactions but merely carries computing steps using numbers of domains in proteins. The method arrives at the end at a "interaction probability value" which do not have a demonstrated real-world utility. Further, the method as claimed may take entirely within the confines of a computer without any communication to the outside world, as there is no outputting step claimed. Thus, the instant claims do not include any tangible result. Further, the claims are directed to computational method of identifying interaction between proteins known in advance to be non-interacting. Such method is not directed to any practical application.

Applicant's response does not address the reasoning of the rejection and is not deemed persuasive.

The rejection is maintained for the reasons of record.

***Claim Rejections - 35 USC § 102.***

7. Claims 1,2,4 are rejected under 35 U.S.C. 102(b) as anticipated by Gomez et al. The rejection is maintained for the reasons of record and further in view of the following.



The first two points of applicant's argument are that Gomez considers a single domain pair compared to a domain combination pair in the instant invention. However, even though specification discusses method based on "plurality of domain pairs" (p. 2, line 10 for example), the instant claims are directed to a single "a domain combination pair" which in Examiner's opinion is equivalent to a domain pair of Gomez.

Further, applicant argues that Gomez does not teach defining and using probability distribution equation. See, p. 417, last paragraph of section 2. The frequency information is used in a probability equation to assign probability to an arbitrary interaction between any two proteins with defined domains. Appearance frequency is presented as a matrix of probabilities. p. 418, section 4.1.

***Conclusion.***

8. No claims are allowed.

Claim 3 is considered to be free of prior art of record or any combination thereof.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb